

## GUIDELINES FOR PREPARING RESEARCH PROPOSALS

Each application should have one Principal investigator (PI). A Co-PI can be named by the PI and is someone making a major contribution to a project. The Co-Principal Investigator is an individual that the PI relies on to assume responsibilities above those of other co- investigators, and during absences. A Co-Investigator is someone making a significant contribution to a project. Co-PI and/or all Co-investigators should review the proposal and indicate their agreement to serve by signing on the cover page next to their names.

The following is a list of items that should be covered in a research proposal, and the recommended length of each section. Sections 1 through 6 should not exceed 10-13 pages.

**1. Abstract:** (up to 350 words).

Briefly: state the background, rationale, and aims of the project; describe the methodology and the analysis of data; and state the significance and relevance of the project.

**2. Specific Aim(s):** (up to 1 page).

Enumerate and describe concisely the *specific* research objective(s) of this application. Emphasize the specific hypotheses to be tested.

**3. Background and Significance, and Innovation:** (1-2 pages).

Describe the background to the present proposal, critically evaluating the existing knowledge on the topic, and specifically identify any gaps in knowledge the project is intended to fill. Describe the goals and objectives that the project intends to achieve. State the importance and relevance of the proposal to health care and medical sciences. Describe the innovative aspects of the proposed project.

**4. Preliminary Studies:** (1-3 pages).

This section may be used to report on preliminary pertinent studies and/or information that help in appraising the experience and competence of the investigator.

**5. Research Design and Methods:** (up to 6 pages).

Describe the research methods and procedures to be used to accomplish the specific aims of the project. Comment critically on them. This section should include, where appropriate:

- a. The specific data to be collected (the parameters to be measured).
- b. The means by which the data will be collected, analyzed and interpreted.
- c. A description of surgical procedures.
- d. The protocols of drug dosage regimens.
- e. The number of subjects per group, and its justification.
- f. A description of any new methodology and its advantage over existing methodologies.
- g. A discussion of potential difficulties and limitations of the work and possible alternatives.
- h. If applicable, include inclusion/exclusion criteria
- i. A tentative time-table for the investigation.
- j. A description of procedures and materials that may be hazardous to personnel and the precautions to be exercised.
- k. A description of the statistical analysis of the data. Biostatistical help is available.

❖ **Human Subjects:**

It is the Principal Investigator's (PI) responsibility to indicate whether human subjects will be involved in any submitted research protocol. All proposals involving human subjects should be reviewed and approved by the IRB before launching the study. For additional information please check the [Guidance Document](#) on Coordinating Submission of Research Proposals to the Research Committee and Institutional Review Board

The following general points should be addressed in the proposal to the extent they help in understanding the proposal by the reviewers. This is distinct from the IRB application.

- a. A description of the subject population including number, gender, age, health status, ethnic groups, etc..., and criteria for inclusion and exclusion and their rationale.
- b. A detailed description that includes: Analysis of data/ power studies and sample size determinations.
- c. Source of material obtained from living subjects in the form of specimens, records, or data. Indicate whether this will be obtained specifically for research purposes or whether use will be made of previously obtained material or material obtained in the course of standard clinical work-up of the patient.
- d. A description of plans for recruitment of subjects, the nature of the information provided to prospective subjects, the method of obtaining consent and, if applicable, a copy of the informed consent form to be used.
- e. Potential risks, their likelihood and seriousness. Describe alternative treatments and procedures that might be advantageous to the subject.
- f. If more than minimal risk exists, state specifically the procedures for protecting against or minimizing these risks. Indicate how provision will be made to ensure necessary medical intervention and prolonged hospital stay in the event of adverse effects to the subject directly resulting from participation in the study.
- g. A discussion of why the risks to the subject are reasonable in relation to the anticipated benefits and in relation to the importance of the knowledge that may result.
- h. It is recommended to submit all IRB forms after the initial RC review when you receive the notice for rebuttal.

For IRB forms and applications please visit these websites:

<http://www.aub.edu.lb/irb/Pages/index.aspx>

❖ **Vertebrate Animals:**

This section complements the "Animal Use Form". The section should include:

- a. Description of the proposed use of the animals in the work described. Identify the species, strain, sex, age, and number of animals to be used.
- b. Justification for their use, especially for their number.
- c. Procedures for ensuring that discomfort, distress, pain and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe use of analgesics, anesthetics, tranquilizing agents and/or comfortable restraining devices, where appropriate, to minimized is comfort, distress, pain and injury.
- d. Description of the method of euthanasia to be used and reason for this choice (if applicable).

For IACUC forms and applications please visit this website:

<http://www.aub.edu.lb/fm/medicalresearch/Pages/AnimalCareFacility.aspx#IACUC>

## **6. Interpretation of Results:**

Describe how the methodology and approach proposed will indeed give the answers to the questions posed and explain how the data collected will be analyzed and interpreted. (This maybe a separate section or an integral part of "Research Design and Methods").

## **7. Potential Limitations:**

A discussion of difficulties and potential limitations of the work and possible alternatives.

## **8. Literature Cited:**

Provide the authors' names, title, journal, volume and page numbers and year of publication, in this order. For books, mention in addition the book title, editors' names (if applicable), publisher, and generate a list of references.

## **9. Budget:**

This should be itemized and detailed enough to allow judgment of its appropriateness based on the description of the research design and methods. A separate justification section may be included if necessary. The budget may be divided into 5 parts:

- a. Personnel. Indicate the percent of time that will be allocated to the proposal. Include salaries and benefits in the budget.
- b. Supplies/Equipment. (For supplies and equipment, make sure that the 35%- 60% shipping expenses for foreign orders are accounted for in the budget). No more than 25% of the proposed budget should be used for purchasing equipment. Justification for any equipment is needed. Final decision for approving purchase of equipment will be made by the RC.
- c. Others, e.g.: animal costs, token compensation for human subjects, including transportation costs. However, hospitalization, extended hospitalization or any another form of medical intervention that is a potential consequence of participation of the subject in a MPP/URB-funded study CAN NOT be covered by any MPP/URB- funded grant. The premiums for an insurance policy that is issued to cover for such events can, however, be paid for by MPP/URB-funded grants.
- d. MPP-funded grants can be used to pay for personnel and reagents needed to carry on a given project.
- e. External technical services are covered provided three conditions are satisfied:
  - *The service is not available at AUB*
  - *A clear explanation of the necessity of performing this outside service is included in the proposal and accepted by the RC committee*
  - *The total cost of all external services does not exceed 25% of the total fund allocated*
  - *For services AUB already offers, a justification is required and needs approval from the RC chair. Also please remember that no more than 25% of your MPP funds may be used to pay for external services.*
- f. All study-related clinical services paid for from MPP/URB-funded grants should be performed at AUBMC. Exceptions require prior approval by the RC chair.
- g. Travel expenses are not covered by the MPP/URB-funded grants.
- h. Miscellaneous: phone calls, photocopy, paper, etc. if fully related to the project and justified.
- i. Statistician fee should not be included in the budget
- j. Funds provided by the URB will be available for one fiscal year (as of July 1-June 30 of the following year).
- k. No duplicate funding will be approved for projects with significant overlap among

separate applications submitted by different PIs or same PI.

- l. Any proposal submitted for additional funding beyond its originally approved funding period will not be considered by the RC.
- m. MPP accounts that are **dormant** for more than three years will be retrieved by the Dean's office.

#### **10. Progress Reports:**

A progress report is required for all renewals and should include the following:

- Project Information: Title, PI/co-PI/co-I, Date of approval, Amount of Fund, Estimated date of completion.
- Brief description of the research proposal and aims of the study.
- The report should include a narrative of accomplishments during the last year. Organize the summary by the aims listed in the original submitted proposal, using separate section for each aim. Describe the obtained data, including tables and figures where appropriate. For clinical research this section should include the number of subjects recruited to date.
- Include a section of what is planned for the next year in order to accomplish the aims of the study.
- Include any significant publication or presentation that resulted from this project.
- Include a section where investigators can list any changes made to their existing research plans or protocols.
- Include a budget justification if there is a major change from the previously approved budget.
- In case of deviation from the timeline related to unavailability of reagents or slow recruitment of subjects, the PI needs to describe the strategies that would be used to accomplish the Aims during the time remaining, with a rationale and adjustments in the corresponding budget for the next year as applicable.
- If there is significant delay in study initiation due to IRB/ IACUC, patient recruitment process or MOH then the PI may ask for a no cost extension by informing the RC administrator. This needs to be done in writing.

#### **11. Timeframe for the Study:**

Describe the duration of the proposed work and the division of labor during that time- period. Set landmarks for accomplishment of tasks or specific aims for the duration of the study. It is important that the budget remains in line with the proposed timeframe. Request for a deferment use of funds or a no-cost extension of a study period beyond the originally approved duration will need approval from the RC chair/co-chairs.

#### **Time Commitment and Funds Available:**

The investigator must clearly state the percent of his/her time he/she will spend on this proposal. Mention other sources of funds for the proposal being now submitted and the amounts provided. Also, a list of other research projects under way should be provided indicating percent time allocated to them, the granting agencies, the funds available and the dates they will expire.

#### **12. Co-investigators:**

This section should include a description of the role of the co-PI and each co-investigator in, and his/her contribution to, the accomplishment of the proposed work. Co-PI and all co-investigators should indicate the percent of their time to be spent on the project.

**13. Online Submission:**

All applications need to be submitted via the [online system](#). No application will be accepted in paper form or after the set deadline. It is important for the PI to ensure that there is a full match between the names of Co-PI and Co-investigators entered in the online submission system and listed on the full proposal. Any mismatch may result in excluding of the proposal from the review process.

**14. Responsibilities of PI and co-PIs and co-Investigators**

The PI is responsible to adhere to all RC guidelines and policies as well as the university guidelines and policies pertaining to research conduct. Deviations may jeopardize current and future funding.

All applicants are required to sign online their acceptance to serve on the proposal.

Electronic signature implies that all applicants have read and agreed with the contents of the application.